Amendment to the Drugs and Cosmetics Rules

1533. SHRIMATI JAMANA DEVI BARUPAL:
DR. T. SUBBARAMI REDDY:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have amended the Drugs and Cosmetics Rules to introduce a cumbersome and expensive procedure for import of medicines w.e.f. the 1st April, 2003;

(b) if so, the details of the new rules and the procedure adopted for licensing;

(c) to what extent the new rules have helped in checking banned drugs; and

(d) whether the Customs has also informed that it is not possible to implement the measures?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b) The Health Ministry has issued Notification No. GSR 604(E) dated 24.08.2001, w.e.f. 01.04.2003 which provides for registration of manufacturing premises of foreign drug manufacturers and the individual drugs prior to their import into the country. Import Licence in Form 10 was already in vogue under Chapter III of the Drugs and Cosmetics Act. What has been added in the present Notification is that all foreign manufacturing sites alongwith their drugs are to be registered in the country before the said drug is permitted for import. The notification has also introduced few other provisions *viz.* enhanced import licence fees, increased validity period of licence, deletion of exemption from requirement of import licence for bulk drugs for actual users, requirement of minimum 60% of retained shelf life for imported drugs and provisions for import of small quantities of new drugs by Government hospitals for treatment of their own patients etc.

As per the new regulation, the manufacturer is to submit documents as specified in Schedule D (I) & D(II) of the Drugs and Cosmetics Rules. Further, the manufacturer is also to submit Power of Attorney to his Indian Agent duly authenticated by the Indian

Embassy where the manufacturer is situated or by a First Class Magistrate in India. For convenience, the details of the registration procedure are available on the website www.cdsco.nic.in.

Registration of a foreign manufacturing site alongwith the manufactured drug is a practice followed world over.

(c) Under the new import regulation, no banned drug is permitted for import into the country for use in India.

(d) No such information has been received.

Empowered action group mechanism

1534. SHRIMATI AMBIKA SONI:
DR. T. SUBBARAMI REDDY:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have sought Cabinet approval to provide more funds under the Empowered Action Group mechanism to enable the State to undertake flexible family planning schemes;

(b) if so, whether the Tenth Five Year Plan has provided a consolidated fund of Rs. 250 crore towards the EAG Scheme;

(c) whether this scheme has been fully approved by the Planning Commission;

(d) if so, the funds provided to each State under this programme;

(e) the States which have utilized funds so far; and

(f) whether any details of the implementation of the scheme and proper utilization of the funds have been obtained from the States?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) Yes, Sir.

(b) Yes, Sir.

(c) Yes, Sir.